



21/Nov/2012

Post market Surveillance and Risk Assessment Re-evaluation

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| |
| Pulse Oximeter VM2105 Finger SpO2 |
| Viamed OBL product |
| Post market Surveillance |
| Risk Assessment |
| Stock References Review |
| Supplier Review |
| Sales Review |
| Country Sales Review |
| Stock Returns Review |
| Design Changes Review |
| User Manuals Review |
| Labels Review |
| Document Updates Review |
| Internal Issues Review |
| Clinical Information Review |
| FDA Incidents Review |
| Carried out by Derek Lamb on 21 / 11 / 12 |

Stock References Reviewed

| Stock Reference | Description |
|-----------------|---------------------------------------|
| 0012103 | Finger Pulse Oximeter Viamed VM 2103. |
| 0012105 | Finger Pulse Oximeter Viamed VM 2105. |
| 0012106 | Finger Pulse Oximeter Viamed VM 2105. |

Comments on Stock references review:

added 0012103 new version

Supplier Information on Main and Component Parts

| Stock Reference | Description | Supplier A/C | Supplier Name | Rating |
|-----------------|---------------------------------------|--------------|-------------------|--------|
| 0012103 | Finger Pulse Oximeter Viamed VM 2103. | 00009300 | Bluepoint Medical | A |
| 0012105 | Finger Pulse Oximeter Viamed VM 2105. | 00009300 | Bluepoint Medical | A |
| 0012106 | Finger Pulse Oximeter Viamed VM 2105. | 00009300 | Bluepoint Medical | A |

Comments on Suppliers:

supplier review is upto date

Sales Information

| Stock Reference | Description | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 |
|-----------------|---------------------------------------|------|------|------|------|------|------|------|
| 0012103 | Finger Pulse Oximeter Viamed VM 2103. | | | | | | | 15 |
| 0012105 | Finger Pulse Oximeter Viamed VM 2105. | | 1 | | 140 | 123 | 294 | 198 |
| 0012106 | Finger Pulse Oximeter Viamed VM 2105. | | | | 145 | 35 | 14 | 17 |

Comments on Sales Information:

Units still selling

New Countries

| Country | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 |
|--------------------|------|------|------|------|------|------|------|
| AU Austria | | | | [X] | | | |
| B Belgium | | | | [X] | [X] | [X] | |
| CAN Canada | | | | [X] | | | |
| CI Canaria Islands | | | | | | [X] | |
| CY Cyprus | | | | | | [X] | |
| CZ Czech Republic | | | | [X] | | [X] | [X] |
| DE Denmark | | | | [X] | | [X] | |
| EG Egypt | | | | [X] | | [X] | |
| ES Estonia | | | | | [X] | [X] | |
| F France | | | | [X] | [X] | | |
| FI Finland | | | | [X] | [X] | [X] | [X] |
| G Germany | | [X] | | | | | |
| GR Greece | | | | [X] | | | |
| IQ IRAQ | | | | | | | [X] |
| IS Israel | | | | [X] | | [X] | |
| J Japan | | | | [X] | | | [X] |
| KE Kenya | | | | | [X] | | |
| KU Kuwait | | | | | | [X] | |
| LEB Lebanon | | | | | | | [X] |
| NE Netherlands | | | | [X] | | | |
| NO Norway | | | | [X] | [X] | [X] | [X] |
| OM Oman | | | | [X] | [X] | | |
| P Poland | | | | [X] | | | |
| PO Portugal | | | | [X] | [X] | [X] | |
| SA South Africa | | | | | | [X] | [X] |
| SAU Saudi Arabia | | | | | [X] | [X] | |
| SI Singapore | | | | [X] | | | |
| SL Slovenia | | | | | [X] | | |
| SP Spain | | | | [X] | [X] | [X] | |
| SW Sweden | | | | | | [X] | |
| SWI Switzerland | | | | [X] | [X] | [X] | [X] |
| TH Thailand | | | | [X] | | [X] | |
| UAE U.A.E. | | | | [X] | [X] | | |
| UK United Kingdom | | | | [X] | [X] | [X] | [X] |
| USA USA | | | | | | | [X] |

Comments on Sales to Countries:

Iraq and Lebanon new countrys.
no issues with new countrys

Comments on Risks with Sales to Countries:

no risks identified with new countrys

Returns Information

| Stock Reference | Fault | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 |
|-----------------|----------------------------|------|------|------|------|------|------|------|
| 0012103 | False reading | | | | | | | 3 |
| 0012105 | Battery lead fault | | | | | | 14 | |
| 0012105 | Dead | | | | | 2 | | 2 |
| 0012105 | Display fault | | | | | | 2 | |
| 0012105 | False reading | | | | 1 | 1 | 3 | |
| 0012105 | Faulty Electronics | | | | 1 | | | |
| 0012105 | Faulty probe | | | | 1 | 4 | 1 | |
| 0012105 | High reading | | | | | | 3 | |
| 0012105 | Intermittent | | | | 1 | 1 | 1 | |
| 0012105 | Intermittent When Squeezed | | | | | 2 | | |
| 0012105 | No Fault Return to Stock | | | | | 1 | | |
| 0012105 | Picking up false signal | | | | 1 | | | |
| 0012105 | Rewired | | | | | 1 | | |
| 0012105 | TEST | | | | | 1 | | |
| 0012105 | Tested OK | | | | | | 2 | |
| 0012105 | Unit dead | | | | 1 | | | |
| 0012106 | Battery lead fault | | | | | 2 | 3 | |
| 0012106 | Case fault | | | | | 1 | | |
| 0012106 | Dead | | | | | 3 | | 2 |
| 0012106 | Display fault | | | | | 1 | | |
| 0012106 | False reading | | | | 2 | 8 | 1 | 2 |
| 0012106 | Faulty Electronics | | | | 1 | | | |
| 0012106 | Faulty probe | | | | | 2 | 1 | |
| 0012106 | High reading | | | | | | 1 | |
| 0012106 | Intermittent When Squeezed | | | | | 1 | | |
| 0012106 | Orange VM2105 problem | | | | | 12 | | |
| 0012106 | Picking up false signal | | | | | 1 | | |
| 0012106 | TEST | | | | 1 | 1 | | |
| 0012106 | Unable to switch on | | | | | 1 | | |
| 0012106 | Uneconomical to repair | | | | | 1 | | |

Comments on Returns:

no noticable returns problems

Comments on Risks with Returns and Potential Re-work:

no reworks done, so no risks

Design Changes / Product Changes

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

n/a

Comments on Risks with Design Changes:

n/a

User Instructions

Showing Documents Filed in F 5 User Instructions

| Document ID | Description | Date Added/Updated |
|-------------|--|--------------------|
| 6976 | VM 2105 Instruction Manual Spanish | 17/03/10 |
| 6975 | VM 2105 Instruction Manual German | 17/03/10 |
| 6974 | VM 2105 Instruction Manual French | 17/03/10 |
| 6973 | VM 2105 Instruction Manual English | 17/03/10 |
| 5080 | VM-2105 Finger Oximeter Quick Start Guide Document | 17/02/09 |

Comments on User Instructions:

no new documents

Comments on Risks User Instructions:

Labels

Showing Documents Filed in F 7 / F 8 Labels

Comments on Labels:

Comments on Risks Labels:

Documentation Updates / Changes

Comments on Document Changes:

only document changes and certificate updates

Comments on Risks with Document Changes:

Review of Issues

Number of Issues reviewed: 11

| Issue ID | Subject |
|----------|---|
| 38524 | Courier Cost - Iraq |
| 38523 | Courier Cost - Iraq |
| 36704 | Microstim Single Page linked to Paypal |
| 35783 | Courier Cost to Benin |
| 35162 | Warranty Terms on User Manual VM2105 |
| 39646 | Request Scanning Item to Sale or return |
| 37896 | Yorkshire Ambulance Consignment Stock |
| 31768 | Book In VM-2105 Orange |
| 38941 | Purchase order qty edit - POR08144 |
| 36465 | Finger oximeter - India special prices |
| 32138 | Web site images |

Comments on Issues:

no comments on issues

Comments on Risks with Issues:

no risks for in issues system

Review of online clinical reports

Do any of the Results indicate a Risk / Problem : No

Do any of the Results indicate outdated Technology : No

Comments on Clinical Search :

Review of online FDA Incident reports

Do any of the Results indicate a Risk / Problem : No

Do any of the Results indicate outdated Technology : No

Comments on Clinical Search :